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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,701	09/30/2003	Roger Petrus Gerebern Vandecruys	JANS-0063	4563

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	

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05/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,701	VANDECRUYS ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-28,30-33 and 35-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-28,30-33 and 35-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/8/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Papers Received: Information Disclosure Statement dated 2/8/07.

Amendment/Response dated 2/8/07.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 20-28,30,32-33 and 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures Rickey et al (USPN 5,792,477 hereafter '477) in view of Shimizu et al (USPN 5,824,339 hereafter '339). The claims are drawn to a solid formulation comprising 9-hydroxy risperidone, or a pharmaceutically acceptable salt, and one or more hydrophilic polymers.

2. The '477 patent teaches a microparticle formulation comprising biodegradable polymers such as poly-lactic acids and 9-hydroxy risperidone, along with other hydrophilic polymers such

as polyvinyl pyrrolidone, and carboxymethylcellulose (col. 5, lin. 29-56; col. 13, lin. 60-col. 14, lin. 11). The hydrophilic polymers are present in an amount from 0.5-2% wt. (*Ibid.*). The reference discloses a method for the delivery of the microparticles to a patient (col. 7, lin. 35-43). The reference is silent to the inclusion of pregelatinized starch yet the inclusion of such a common excipient is well known it the art as seen in the '339 patent.

3. The '339 reference discloses antibiotics in combination with various water-soluble polymers (col. 5, lin. 9-35). The hydrophilic polymers include hydroxypropylcellulose with a viscosity between 1-150,000 cps (col. 4, lin. 55-60), and hydroxypropylmethylcellulose with a viscosity between 1-40,000 centistokes (col. 5, lin. 1-8). The formulation can comprise both celluloses at prescribed ratios (col. 6, lin. 52 – 62), in addition to further excipients such as pregelatinized starches and other well-known excipients (col. 6, lin. 42). One of ordinary skill in the art would have been motivated to include the viscous hydroxypropyl cellulose polymers of the '339 reference in order to improve the stability of the microparticle formulation. Further since both reference comprise similar components such as carboxymethylcellulose and other hydrophilic polymers, an artisan of ordinary skill would be able to simply substitute the viscous polymers in order to improve the stability.

4. Regarding the media of changing ionic strength, it is the position of the Examiner that such a limitation is irrelevant to the structure of the tablet formulation and holds no patentable weight. The structure of the tablet is identical to the combination in the prior art. Further since the fluid is within the gastrointestinal tract, it merely means that the tablet is taken orally, which the combination of the prior art is. For these reasons the limitations are given no patentable weight.

5. With these things in mind it would have been obvious to combine the highly viscous polymers of the '339 patent with the formulation of the '477 patent in order to provide stability and a controlled release to the microparticles. The '447 suggests the inclusion of carboxymethylcellulose, while the '339 patent discloses the use of either carboxymethylcellulose or hydroxypropylcellulose polymers. It would have been obvious to combine the teachings with an expected result of a control releasing formulation of a solid dosage from.

6. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rickey et al (USPN 5,792,477 hereafter '477) and Yajima et al (USPN 5,972,373 hereafter '373). The claims are drawn to a controlled release formulation comprising 9-hydroxyrisperidone and hydrophilic polymers.

7. As discussed above the '477 patent discloses a formulation comprising 9-hydroxyrisperidone and various hydrophilic polymers. The reference however is lacking a disclosure of the particular polymers of applicant.

8. The '373 patent discloses a taste masking formulation for various antibiotic agents (abstract). The formulation comprises hydrophilic polymers including hydroxypropylcellulose, hydroxypropylmethylcellulose, pregelatinized starch, and cyclodextrins (col. 3, lin. 13 – 56). Since similar antibiotics are masked by this formulation (col. 2, lin. 38-48), a skilled artisan would have been motivated to use the polymers of the '373 patent in order to impart stability and taste masking properties to the presentation.

9. Regarding claims that recite specific ratios and concentrations, it is the position of the examiner that such limitations do not impart patentability on the claims, since they merely

represent an optimize range that can be determined through routine experimentation. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

10. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

11. With these things in mind it would have been within the level of skill in the art to combine the antibiotic of '477 with the hydrophilic polymers of '373 in order to impart stability and taste masking properties on the formulation. A skilled artisan would make this combination with an expected result of a stable, pleasantly tasting antibiotic formulation.

Response to Arguments

12. Applicant's arguments filed 2/8/07 have been fully considered but they are not persuasive. Applicant argues that;

a. The combination of references does not obviate the claims since the '447 patent does not disclose a solid tablet comprising pregelatinized starch.

13. Regarding this argument, it is the position of the Examiner that the combination of the '447 and '339 patents sufficiently obviates the claims. Applicant argues that the '447 patent fails

to teach a solid tablet comprising pregelatinized starch and 9-hydroxyriperidone. The Examiner does not rely upon for the '447 patent for such teachings. The '447 patent is relied upon for its disclosures of microparticles comprising 9-hydroxyrisperidone along with common controlled releasing carriers, that act as functional equivalents to pregelatinized starch. The excipients include polyvinylpyrrolidone and carboxymethylcellulose. These are also seen in the '447 patent establishes their commonality in the art. Though the '447 patent exemplifies an injectable formulation, the microparticles are solid and it is the position these microparticles would be incorporated into the formulation of the '339 in order to provide an improved release. The '339 patent provides the pregelatinized starch, and mixture of polymers required by the claims. The reference establishes the level of skill in the art regarding controlled release rates and their relationship to the ratio of hydrophilic to hydrophobic polymers (col. 7, lin. 50-60). It is the position of the Examiner that one of ordinary skill in the art would be motivated to include the microparticles of the '447 into the formulation of the '339 patent in order to provide an improved controlled release formulation, with better stability and a uniform release. For these reasons the claims remain obviated by the claims.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER